

REMARKS

Claims 1-16 and 25 are pending.

The Examiner requires a "legible" copy of the reference cited in the IDS of October 28, 2004. Applicants request clarification of what is meant by legible. If the copy submitted was a poor quality such that the words cannot be made out, applicants would be happy to submit a further copy. If the Examiner is referring to the fact that the document is only available in the German language, applicants note that the article "Isolation of cDNA clones for genes showing enhanced expression in barley leaves during dark-induced senescence as well as during senescence under field conditions" by Klever-Janke and Krupinska (Planta (1997) pgs. 332-340), which was included in the original IDS submitted in April 2000, covers the essence of said dissertation and thus provides a concise explanation of the relevance thereof.

As requested by the Examiner, the wording of claims 2-5, 8 and 25 has been amended.

Claims 1-16 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirements. Applicants respectfully traverse this rejection.

In the decision of *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), the court held

1. that a patent specification which includes by example a process for obtaining human-insulin-encoding cDNA, and which describes the protein (amino acid sequence) that the cDNA encodes, but which does not describe the structure of the claimed cDNA in terms of its nucleotide sequence, does not comply with the written description requirement;

2. that the cDNA nucleotide sequence for rat insulin, as described by the patentee, did not provide a written description adequate to claim the genus of vertebrate or mammalian insulin cDNA; and
3. that the description in the respective patent of the amino acid sequences of the A and B chains constituting human insulin does not provide a written description of cDNA encoding for human insulin, because the structure of the protein itself is insufficient to positively determine the nucleotide structure of the corresponding natural DNA due to degeneracy of the genetic code.

The application at hand, in contrast, claims an isolated DNA encoding for barley HPPD on the basis of the genomic DNA sequence of the *H. vulgare* HPPD. Therefore, the application at hand does not

1. claim a process for obtaining a cDNA without disclosing the claimed DNA in terms of its nucleotide sequence;
2. claim a taxonomic phylum (vertebrates) on the basis of a cDNA nucleotide sequence isolated from a single species; or
3. claim a DNA on the basis of a protein sequence.

With respect to item 2), it is important to realize that in the animal taxonomy a "genus" is a so-called taxon that is used to subsume related species. The term "vertebrates" describes a so-called "phylum". The taxon phylum as used in the hierarchy of animal taxonomy covers (in hierarchical order) the class, the order, the family, the genus and the species.

Thus, the patent in the *University of California* case cited by the Examiner claimed all DNAs encoding for insulin proteins from the phylum *Vertebrata*, based on a cDNA encoding the insulin protein from the species *Rattus norvegicus*. The present application, however, as

mentioned above, claims only a DNA encoding for genus *Hordeum* on the basis of the genomic DNA sequence of the species *H. vulgare*. There is a significant difference between a claim covering an entire phylum, and a claim covering only a genus.

Moreover, due to the high degree of identity, it is justifiable to claim a certain genus (in the taxonomic sense) on the basis of an isolated DNA from a single species. The high degree of conservation between DNA sequences encoding for HPPDs within the family *Poaceae* (formerly *Graminae*) is exemplified by a comparison between the HPPD from *Hordeum vulgare* and *Oryza sativa* (see the enclosed Declaration, Figures 1 and 2). The homology between the coding region of these DNAs is 84%, although these organisms do not belong to the same genus. Accordingly, one would reasonably conclude that the degree of homology between genes encoding for HPPD from genus *Hordeum* must be at least above 95%, and likely even higher.

It is universally accepted in the scientific community – and provides the basis for phylogenetic studies based on the so-called "molecular clock" (a technique in genetics, which researchers use to date when two species diverged on the basis of differences between their DNA sequences) – that the degree of homology between a given gene and its orthologs or paralogs within the same genus is higher than between a given gene and its orthologs or paralogs belonging to a different genus/tribe.

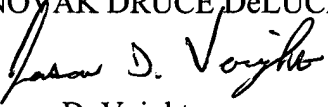
Thus, on the basis of techniques that are comprehensively disclosed in the specification of the present application (Examples 1 and 2) or additional established methods and techniques well known to a person having ordinary skill in the art at the time of the invention, the isolation of genes encoding for HPPDs from other members of the genus *Hordeum* by e.g. simple PCR cloning approaches or the screening of cDNA libraries using the disclosed DNA as a probe is a routine task for a skilled person.

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Thus, applicants urge that the presently claimed subject matter is patentable.

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